Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Proposed Maximum Residue Limit PMRL2014-05

Sedaxane

(publié aussi en français)

21 January 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2014-05E (print version)
H113-24/2014-05E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2014

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on Crop Subgroup 6C (dried shelled pea and bean, except soybeans), and the addition of all crops in Crop Group 15 (cereal grains) and in Crop Subgroup 20A (rapeseed subgroup), to the product label of Vibrance 500FS Seed Treatment, containing technical grade sedaxane, is acceptable. The specific uses approved in Canada are detailed on the label of Vibrance 500FS Seed Treatment, *Pest Control Products Act* Registration Number 30438. Furthermore, the PMRA has concluded that the addition of the new use on potatoes to the new product Vibrance Potato, containing technical grade sedaxane, for the control of fungal diseases on potatoes is acceptable. The specific uses approved in Canada are detailed on the product label of Vibrance Potato, *Pest Control Products Act* Registration Number 31041.

The evaluation of these sedaxane applications indicated that the end-use products have merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for sedaxane is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to be added to the MRLs already established for sedaxane, are as follows.

Table 1 Proposed Maximum Residue Limits for Sedaxane

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Sedaxane	1*H*-pyrazole-4-carboxamide, *N*-[2-[1,1'-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-	0.02	Crop Subgroup 1C (tuberous and corm vegetables)
		0.01	Crop Subgroup 6C (dried shelled pea and bean, except soybean), borage seeds, buckwheat, echium seeds, field corn, flaxseeds, gold of pleasure seeds, hare's ear mustard seeds, milkweed seeds, mustard seeds (oilseed type), oil radish seeds, pearl millet, popcorn grain, poppy seeds, proso millet, sorghum, sweet corn kernels plus cob with husks removed, sweet rocket seeds, teosinte, wild rice

[1] ppm = parts per million

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Refer to Table 2 for a comparison, where different, of the Canadian MRLs and American tolerances for sedaxane. The proposed Canadian MRLs for borage seeds, echium seeds, flaxseeds, gold of pleasure seeds, hare's ear mustard seeds, milkweed seeds, mustard seeds (oilseed type), oil radish seeds, poppy seeds and sweet rocket seeds are identical to the American tolerance recommended for the rapeseed subgroup 20A. The proposed Canadian MRLs for Crop Subgroup 6C, corn and sorghum are identical to the corresponding recommended American

tolerances. The proposed Canadian MRL for Crop Subgroup 1C is identical to the American tolerance recommended for potato. There are no American tolerances established for buckwheat, pearl millet, proso millet, teosinte and wild rice. Currently, Codex MRLs[1] (Codex MRLs searchable by pesticide or commodity) have not been established for sedaxane in/on any commodity.

Table 2 Comparison of Canadian MRLs and American Tolerances (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)
Pearl Millet	0.01	Not Established
Proso millet	0.01	Not Established
Teosinte	0.01	Not Established
Wild rice	0.01	Not Established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for sedaxane up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data from trials conducted in Canada and the United States at the label and exaggerated rates for sedaxane in corn, dry bean, dry pea, potato and sorghum were submitted to support the use expansion of this active on the Vibrance 500FS label, and to register the new end-use product Vibrance Potato. Previously reviewed residue data from field trials conducted in/on canola, barley and wheat at label and exaggerated rates were reassessed in the framework of this petition. In addition, processing studies in treated field corn and potato were submitted and reviewed to determine the potential for concentration of residues of sedaxane into processed commodities, and previously reviewed processing studies for barley, canola and wheat were reassessed in the framework of this petition.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for sedaxane was based upon the submitted field trial data and the recommendation of the OECD calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s)

Commodity	Application Method/ Total Application Rate	DAP[1]	Residues (ppm)[2]		Experimental Processing Factor
			Min	Max	
Barley grain	Seed treatment/ 5–5.2 g a.i. per 100 kg seed	At maturity; 95–119	<0.01	<0.01	Could not be determined as residues were not quantified in the grain and processed commodities.
Canola	Seed treatment/ 5.9–7.5 g a.i. per 100 kg seed	84–232	<0.01	<0.01	Could not be determined as residues were not quantified in the seed and processed commodities.
Dry bean seed	Seed treatment/ 2.4–5.0 g a.i. per 100 kg seed	101–148	<0.01	<0.01	Not required
Dry pea seed	Seed treatment/ 4.1–6.0 g a.i. per 100 kg seed	75–131	<0.01	<0.01	Not required

Commodity	Application Method/ Total Application Rate	DAP[1]	Residues (ppm)[2]		Experimental Processing Factor
			Min	Max	
Field corn grain	Seed treatment/ 40 g a.i. per 100 kg seed	113–177	<0.01	<0.01	Could not be determined as residues were not quantified in the grain and processed commodities.
Grain sorghum grain	Seed treatment/ 44.4–57.5 g a.i. per 100 kg seed	107–168	<0.01	<0.01	Not required
Popcorn grain	Seed treatment/ 40 g a.i. per 100 kg seed	210	<0.01	<0.01	Not required
Potato	Seed piece treatment/ 2.2–2.7 g a.i. per 100 kg seed	71–130	<0.01	<0.0184	0.75x (chips); 1.1x (flakes)
Sweet corn kernels plus cob with husks removed	Seed treatment/ 29.7–40 g a.i. per 100 kg seed	40–121	<0.01	<0.01	Not required
Wheat grain	Seed treatment/ 5–5.2 g a.i. per 100 kg seed	At maturity; 97–130	<0.01	<0.01	Could not be determined as residues were not quantified in the grain and processed commodities.

[1]Days after planting.
[2]Combination of trans-isomer SYN508210 and cis-isomer SYN508211;

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of sedaxane. Residues of sedaxane in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.